DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 606, 607, 610, 630, 640, and 660

[Docket Nos. 98N–0581, 98N–0607, and 98N–0815]

Blood Safety Initiative: Extension of Comment Period on Proposed Rules and Announcement of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; announcement of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and is extending to December 22, 1999, the comment period on two proposed rules entitled ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents,'' and ''General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors.'' FDA is also extending to December 22, 1999, the comment period on the advance notice of proposed rulemaking (ANPRM) entitled ''Plasma Derivatives and other Blood-Derived Products; Requirements for Tracking and Notification.'' The purpose of the meeting is to provide a public forum for gathering information and views regarding the proposed rules and the ANPRM. The comment periods are being extended to provide time for the submission of comments that may result from the issues discussed at the public meeting.

DATES: The public meeting will be held on Monday, November 22, 1999, from 8:30 a.m. to 12 noon. Submit written comments for ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents,'' ''General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors,'' and ''Plasma Derivatives

and other Blood-Derived Products; Requirements for Tracking and Notification'' by December 22, 1999.

ADDRESSES: The public meeting will be held at the National Institutes of Health (NIH), NIH Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the appropriate docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For registration and meeting information: Kathy Eberhart, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–1317, FAX 301–827–3079, e-mail: eberhart@cber.fda.gov.

For information about this document: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 19, 1999 (64 FR 45340 and 45355), FDA published two proposed rules that were intended to help protect the safety and ensure the quality of the nation's blood supply and to promote consistency in the industry. The document entitled ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents'' (64 FR 45340) [Docket No. 98N–0581] proposed to revise the general biological product standards by updating the hepatitis B virus (HBV) and human immunodeficiency virus (HIV) testing requirements, by adding testing requirements for hepatitis C virus (HCV), human T-lymphotropic virus (HTLV), and by adding requirements for licensed supplemental (i.e., additional, more specific)

testing when a donation is found to be repeatedly reactive for any of the required screening tests for evidence of infection due to communicable disease agents.

The document entitled ''General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors'' (64 FR 45355) [Docket No. 98N–0607] proposed to require blood and plasma establishments to notify donors of their deferral due to test results for communicable disease agents or failure to satisfy suitability requirements with the intent of reducing the risk of transmission of communicable disease through the use of blood, blood components, and blood derivatives. Blood and plasma establishments would notify donors that they have been deferred and the reason for the deferral; provide information concerning appropriate medical follow up and counseling; describe the types of donations the donors should not make in the future; and discuss the possibility that the donor may be found suitable in the future, where appropriate. FDA provided until November 17, 1999, to submit comments on these proposed rules.

The ANPRM entitled ''Plasma Derivatives and other Blood-Derived Products; Requirements for Tracking and Notification'' (64 FR 45383, August 19, 1999) [Docket No. 98N–0815] announced FDA's intention to propose regulations to require certain blood-derived products, including certain plasma derivatives, be tracked from a U.S. licensed manufacturer, through the distribution network, to any patient having custody of the product. FDA also announced its intention to propose to require notification of consignees and patients having custody of a blood-derived product or an analogous recombinant product in the event the product is associated with a potential increased risk of transmitting a communicable disease, as determined by FDA or by a U.S. licensed manufacturer. FDA provided until November 17, 1999, to submit comments on the ANPRM.

II. Comments

Interested persons may submit written comments on these proposed rules and the ANPRM to the Dockets Management Branch (address above) by the date listed above. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the appropriate docket number found in brackets in the heading of this document.

If time permits, comments may be taken from the floor. FDA is requesting that those persons making oral presentations at the public meeting also submit their statements in writing by December 22, 1999, as described above, to ensure their adequate consideration. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Registration and Requests for Oral Presentations

Mail or fax registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to Kathy Eberhart (address above) by Monday, November 15, 1999. If you do not intend to make a presentation, registration is not required. However, all interested persons are encouraged to pre-register.

If you need special accommodations due to a disability, please contact Kathy Eberhart at least 7 days in advance.

IV. Transcripts

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16,

Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript will also be available on CBER's website at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: November 2, 1999.

William K. Hubbard
Senior Associate Commissioner for
Policy, Planning, and Legislation

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